510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K040327

B. Analyte:
Cannabinoids, Cocaine

Type of Test:
Qualitative immunoassay

Applicant:
Accu-Stat Diagnostics, Inc.

Proprietary and Established Names:
Accu-Stat Home Drug Test for Marijuana (THC)
Accu-Stat Home Drug Test for Marijuana & Cocaine (THC, COC)

C. Regulatory Information:

1. Regulation section:
   Test Kit, Multiple Drugs of Abuse, Over the Counter, Unclassified
   862.3870, Enzyme Immunoassay, Cannabinoids
   862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites

2. Classification:
   II

3. Product Code:
   MVO, LDJ, DIO, respectively

4. Panel:
   Toxicology (91)

Intended Use:

5. Intended use(s):
   Refer to Indications for use.

6. Indication(s) for use:
   The assays are screening tests for the rapid detection of THC and THC & Cocaine in human urine at cut-offs of 50 ng/mL for THC and 300 ng/mL for cocaine. The tests are for over-the-counter consumer use as the first step in a two step process to provide consumers with information concerning the

presence or absence of drug in a urine sample. Information, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is provided.

The device is for in vitro diagnostic use.

7. Special condition for use statement(s):

   The assays provide only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

   The assay is for OTC use.

   The materials necessary for confirmation testing are provided with the screening device. Materials, as well as confirmation testing are provided to the consumer at no additional charge. The consumer pays for shipment of the sample to the laboratory.

8. Special instrument Requirements:
   Not applicable. The device is a visually read single-use device.

Device Description:

The product is a single-use visually read cassette device. A plastic housing contains the test strip. A plastic sample dispenser is also provided. Operators add several drops of the urine to the sample well to initiate the test. The test employs a traditional immunochromatographic technology.

The devices are manufactured for them by ACON. The products received prescription clearance under ACON THC One Step Marijuana Test Device, k003557 and ACON Multi-Drug Multi-Line Test Device, K020313.

D. Substantial Equivalence Information:

1. Predicate device name(s):
   Phamatech At Home Drug Test for Marijuana and Cocaine
2. Predicate K number(s):
   K991641
3. Comparison with predicate:

   The devices are for the qualitative determination of the same analyte(s) in the same matrix, and utilize the same cutoff concentrations. Both are visually-

read single use devices for over-the-counter use that includes confirmation testing. The manufacturer of the products differs, as well as their labeling.

Standard/Guidance Document Referenced (if applicable):

The sponsor did not reference any standards in their submission.

Test Principle:

The test employs lateral flow immunochromatographic technology.

Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

E. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision and accuracy of the product in the hands of the consumer were demonstrated in a consumer study. 503 consumers, reading 1 or 2 test samples each, participated in the blinded study. Test samples were drug free urine, filtered and spiked with the targeted drug. Concentrations of the prepared sample pools were confirmed with GC/MS. The amount of drug found by GC/MS was recovered between 80 to 116% of the targeted concentration level.

Details concerning the consumer study include:
The number of lots of product used: not specified
Number of operators: 171 for THC and 234 in the THC and Cocaine study
Operator: lay users, with approximately 10% indicating they previously used drugs of abuse testing products.
Testing Facility: 4 geographic locations, but the types of settings were not specified.

A consumer questionnaire was also administered to evaluate labeling effectiveness. Only one question was asked, however, and the question did not determine whether labeling adequately alerted users to the limitations of home use testing devices. That question was "Was the test easy to interpret?" All but 1 participant responded that it was easy to interpret.

Results of the study are presented below:

THC CONSUMER TEST RESULTS

Sample Solution	Concentration	(n) Studies	Positive (+)	Negative (-)
A	200% THC (+)	21	21 (100)	0 (100)
B	150% THC (+)	34	34 (100)	0 (100)
C	125% THC (+)	30	29 (96.7)	1
D	75% THC (-)	34	1	33 (97.1)
E	50% THC (-)	32	0 (100)	32 (100)
H	0% THC (-)	20	0 (100)	20 (100)
Total Tests		171*		

COCAINE CONSUMER TEST RESULTS

Sample Solution	Concentration	(n) Studies	Positive (+)	Negative (-)
A	200% COC (+)	21	21 (100)	0 (100)
E	150% COC (+)	32	32 (100)	0 (100)
C	125% COC (+)	30	29 (96.7)	1
F	75% COC (-)	33	0 (100)	33 (100)
G	50% COC (-)	30	0 (100)	30 (100)
H	0% COC (-)	20	0 (100)	20 (100)
Total Tests		166*		

Parenthesis, percentage of correct results
Overall percentage of correct results: 231/234 (98.7%)
* Solutions A,C, and E were spiked with both drugs yielding 234 total studies

b. Linearity/assay reportable range:
Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):

The device has an internal process control. As described in the Rx version of the product, it informs users only that enough urine was added to the test.

d. Detection limit:
Issues were addressed previously in the prescription submission.

e. Analytical specificity:
Issues were addressed previously in the prescription submission.

f. Assay cut-off:
The identified cutoff concentration(s) of the assay(s) are recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA).

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:
   a. Method comparison with predicate device:

   Accuracy of the device in the hands of the consumer when evaluating spiked samples is demonstrated in the precision section, above.

   Issues concerning clinical accuracy were addressed previously in the prescription submission.

   b. Matrix comparison:
   Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   b. Clinical specificity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not applicable.
5. Expected values/Reference range:
   Not applicable.

Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.